This Page Is Inserted by IFW Operations and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

Lift's Act of Mariagno

(19) **(19)**

Europäisches Patentamt

European Patent Office

Office européen des brevets



EP 0 737 450 A1

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication: 16.10.1996 Bulletin 1996/42

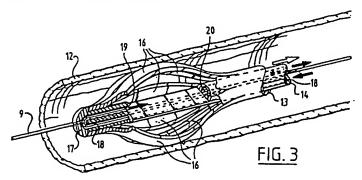
(51) Int. Cl.6: A61F 2/01, A61B 17/22

(11)

- (21) Application number: 96200976.7
- (22) Date of filing: 09.04.1996
- (84) Designated Contracting States: BE CH DE FR GB IE IT LI NL
- (30) Priority: 10.04.1995 NL 1000105
- (71) Applicant: CORDIS EUROPA N.V. NL-9301 LJ Roden (NL)
- (72) Inventor: Boudewijn, Alexander Christiaan 9351 KS Leek (NL)
- (74) Representative: 't Jong, Bastiaan Jacobus Arnold & Siedsma, Advocaten en Octroolgemachtigden, Sweelinckplein 1 2517 GK Den Haag (NL)
- (54) Catheter with filter and thrombidischarge device

(57) This invention relates to a catheter comprising a tube-like basic body with a distal and a proximal end, wherein the catheter comprises an expandable filter element at the distal end and a device for reducing thrombi in size and removing them.

The filter element is formed by a number of stripshaped wall sections of the basic body defined in between longitudinal cuts evenly distributed around the circumference and furthermore comprises a means for moving the sections of the basic body positioned on either side of the wall sections towards each other in order to make the wall sections bend outwards.



Description

The invention relates to a catheter comprising a tube-like basic body with a distal and a proximal end and wherein an expandable filter element has been arranged to the distal end. Such a catheter is introduced into a patient during surgery in order to collect thrombi and to prevent that these finish up for instance in the vascular system of the lungs and cause an embolism. The filter element of such a catheter is usually positioned in the vena cava.

The collected particles are removed or reduced in size by withdrawing the filter or by disintegrating them locally

When removing the particles by withdrawing the catheter, there is a risk that they might come loose of the filter element and still will finish up at unwanted positions in the blood stream. Removal of the particles by allowing them to disintegrate locally can take up quite some time.

The object of the invention is to provide a catheter of the type as described in the preamble with which the said drawbacks are removed.

This aim is achieved with the catheter according to the invention as characterised in claim 1. As a result the 25 thrombi collected by the filter element can be fragmented and removed from the body. This can be done at regular intervals or just before the catheter is removed from the body of the patient. The wall sections defined in between the longitudinal cuts can bend outwards until they make contact with the wall of the blood vessel inside of which the filter element is placed. The thrombi arrested by the filter element are sucked into and remain enclosed within the filter element untill these are removed. Prior to introducing the catheter, the wall sections are straightened by moving the ends of the basic body situated on either side of the wall sections away from each other. As a result the catheter will obtain a small cross-section equal to that of the basic body not provided with the longitudinal cuts, so that the catheter can be introduced with a minimum of traumatic

A very suitable embodiment of the device for reducing the thrombi in size and removing them is characterised in claim 2. A stream of liquid under pressure, supplied via the pressure lumen, flows out of the jet nozzle in the form of a jet and engages sections of thrombi which are fragmented due to the energy of the jet. The thrombus fragments are conveyed by the jet to the discharge opening and removed via the discharge lumen.

A very suitable embodiment of the catheter according to the invention is characterised in claim 3. By moving the inner and outer tube-like bodies in relation to one another the strip-shaped wall sections can be bent outwards or stretched respectively. On introducing the catheter, the inner tube-like body is moved as much as possible in the relatively distal direction inside the outer tube-like body, so that the strip-shaped wall sections will be stretched. After positioning the distal end of the cath-

eter, the inner tube-like body is moved in the relatively proximal direction in the outer tube-like body, as a result of which the strip-shaped wall sections will bend outwards and consequently form the filter element.

Additionally the measure as set out in claim 4 is preferably employed. The inner tube-like body is in that case essentially made in the form of a suction catheter, wherein all parts required for the reduction and removal device are received in this inner tube-like body.

By employing the measure as set out in claim 5 it is ensured that the reduction and removal device can continue to work properly without getting blocked. On activating the reduction and removal device, first those parts of the thrombi extending as far as in between the bent wall sections of the filter element are engaged, after which gradually the entire structure is fragmented and removed.

Preferably the measure as set out in claim 6 is employed. The discharge lumen does not need to be connected in that case to a separate source of suction. As a result of the ejector action a sufficient flow is maintained in the discharge lumen without applying additional suction.

The invention will be explained in greater detail in the following description with reference to the attached drawings.

Figure 1 shows schematically the application of a catheter according to the invention.

Figure 2 illustrates the distal end of a catheter according to the invention when being positioned in the blood vessel.

Figure 3 shows a view corresponding to that of figure 2 in which case the filter element is illustrated in working state.

As is illustrated schematically in figure 1, a catheter 1 according to the invention is introduced into a patient 2, in order to position a filter element 3 at the distal end of the catheter 1 inside a blood vessel, in particular in the vena cava.

The catheter 1 comprises a tube-like basic body 4 with a filter element 3, still to be explained in greater detail, at the distal end and a connecting member 5 at the proximal end.

The connecting member 5 comprises in this example of an embodiment a haemostatic valve 6 through which a guide wire 9 is advanced, which is employed in the usual manner for the purpose of positioning the catheter 1.

Furthermore the connecting member 5 comprises addischarge connection 7 which is connected with the discharge lumen in the basic body 4 and a pressure connection 8 which is connected with a pressure lumen in the basic body 4.

The basic body 4 of the catheter 1 comprises an outer tube-like body 13 and an inner tube-like body 14 received therein in a, in a longitudinal direction, movable manner. The outer tube-like body 13 and the inner tube-like body 14 are connected to each other with their distal ends. At the very end, a tip 17, made of a soft material,

has been arranged in order to prevent trauma on introduction of the catheter 1 into the blood vessel 12.

At the distal end of the outer tube-like body 13, a number of longitudinal cuts 15, distributed evenly around the circumference, have been arranged defining strip-shaped wall sect tions 16 in between them. The wall sections 16 together form the actual filter element. By pulling the inner tube-like body 14 at the proximal end of the catheter 1 over a limited distance in relation to the outer tube-like body 13 outwards, the strip-shaped wall sections are put under a compression load in a longitudinal direction as a result of which they will bend outwards in the direction illustrated in figure 3. The relative displacement of the outer tube-like body and the inner tube-like body is chosen in such a manner, that the wall sections 16 make a good contact with the inner wall of the blood vessel 12.

It will be clear that thrombi as from a certain size, flowing through the blood vessel 12, will be collected by the filter element formed by the wall sections 16 bending outwards, and that at the same time the blood can flow in a normal manner through these wall sections.

The inner tube-like body 14 comprises the aforementioned pressure lumen 18 connected with the pressure connection 8. In the manner illustrated in figure 3, 25 the pressure lumen 18 is connected with a channel section extending backwards in proximal direction forming a jet nozzle 19. The jet nozzle 19 is directed at a discharge opening 20 which forms the end section of a discharge lumen in the inner tube-like body 14, which is 30 connected in the above described manner with the discharge connection 7.

In addition to the pressure lumen and the discharge lumen, the inner tube-like body 14 comprises another lumen for the guide wire 9.

End sections of thrombi collected by the filter element will extend as far as inside the space defined by the wall sections 16 bending outwards. In order to reduce the thrombi in size and remove them, liquid under pressure is supplied to the pressure connection 8, so that a powerful liquid jet leaves the pressure nozzle 19 in the direction of the discharge opening 20. The end sections of the thrombi are engaged by this liquid jet and reduced in size by mechanical action and entrained through the discharge opening 20 in the discharge lumen. In order to stimulate the discharge flow, a vacuum source can be connected to the discharge connection 7. As a result of the suction action, the thrombi are gradually sucked further into the space defined by the wall sections 16 where they are gradually reduced in 50 size and ultimately removed via the discharge lumen.

The jet nozzle 19 and the discharge opening 20 can, in a suitable manner, be arranged and dimensioned in relation to each other in such a way that the flow of liquid leaving the jet nozzle 19 creates an ejector-action as a result of which a separate flow is created in the discharge lumen towards the proximal end without additional suction action at the discharge connection 7.

It will be clear that the thrombi reduction and discharge device, and the filter element likewise, can be embodied in different ways. The reduction and discharge device may for instance comprise several, for instance two, jet nozzles with corresponding discharge openings. It will also be possible to arrange the reduction and discharge device at for instance the relatively distal end of the filter element, that is to say outside the space defined by the wall sections bending outwards. Another possibility is a combination of a reduction and discharge device both in and outside the filter element.

When the filter catheter has carried out its task, and there is no longer a danger for the patient of an embolism forming, the catheter can be removed. In order to achieve this, the inner tube-like body is moved in relation to the outer tube-like body in a relatively distal direction, so that the wall sections 16 bending outwards are stretched again into the state illustrated in figure 2. The catheter will then have resumed its original small cross-section, so that it can be withdrawn easily.

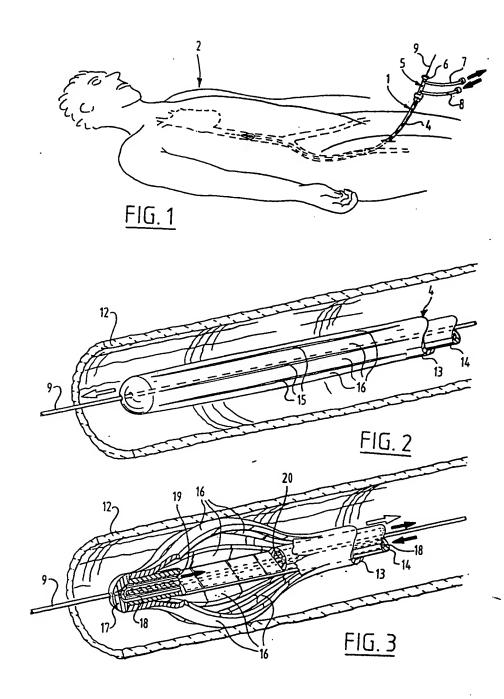
Claims

- Catheter comprising a tube-like basic body with a
 distal and a proximal end, wherein the catheter
 comprises at the distal end an expandable filter element formed by a number of strip-shaped wall sections of the basic body defined in between
 longitudinal cuts evenly distributed around the circumference, and furthermore comprising a means
 for moving sections of the basic body situated on
 either side of the wall sections towards each other
 in order to make the wall sections bend outwards,
 and a device for reducing thrombi in size and
 removing them
- Catheter as claimed in claim 1, wherein the thrombi reduction and discharge device comprises a jet nozzle connected with a pressure lumen inside the basic body pointing in the proximal direction and a discharge opening, formed opposite the jet nozzle, which is connected to a discharge lumen.
- Catheter as claimed in claim 1, comprising an outer tube-like body and an inner tube-like body received inside it in a movable manner, which are connected to each other at their distal ends and wherein the strip-shaped wall sections have been formed in the outer tube-like body.
- Catheter as claimed in claim 2 and 3, wherein the pressure lumen and the discharge lumen have been received inside the inner tube-like body.
- 55 5. Catheter as claimed in claim 4, wherein the jet nozzle and the discharge opening are positioned inside the longitudinal section of the catheter wherein the longitudinal cuts extend.

€

 Catheter as claimed in one of the claims 2 - 5, wherein the jet nozzle has been positioned and dimensioned in relation to the discharge opening in such a way that they form an ejector.

EP 0 737 450 A1



EP 0 737 450 A1



EUROPEAN SEARCH REPORT

EP 96 20 0976

DOCUMENT			EP 95 20 0976
DOCUMENTS CO	NSIDERED TO BE RELI		_
Category Citation of document	NIDERED TO BE RELI with indication, where appropriate, art passages	EVANT	7
1' 1U3-A-5 A52 000 4		Relevant to chian	CLASSIFICATION OF THE
* abstract; figur	BAJAJ) 1 October 1001	1	APPLICATION (INC.6)
l., I rigui	res *	1,3	A61F2/01
Y FR-A-2 686 642 (AMUS) 28 May 1988 ent *	1 1	A61817 (20
the whole de	AMUS) 20 May 1000	1 1	A61B17/22
I more docum	ent *	1,3	1
A EP-A-B 442 ETG 45		- 1 - 1	1
* abstract. 6:	ORDIS) 21 August 100-	1 1	1.
* abstract: figure	ORDIS) 21 August 1991	2,6	
A US-A-4 722 540 4	(OLEY) 9 February 1988	1 1	1
* abstract. 6:	OLEY) 9 February ton	- 1 - 1	1
Tigure	2 * 1 CDI Hary 1988		1
1 1			1
1 1		1 1	1
		1 1	4
1 1		1 1	1
1 1		1 1	
1 1		1 1	1
		1 1	- 1
1 1		1 1	. 1
1 1		1 1	1
1 1		1 1	1
1 1		1 h	
1 1		SE	CHNICAL FIELDS
1 1		1	
		A61	
1 1	1	A61	в 1
1 1	i	1 1	1
1 1	1		1
1 1	ľ	- 1	1
1 1	1	1	1
1 1	1	1	ł
1 1	1	- 1	I
1 1	- 1	i	I
1 1	i	- 1	1
1 1	1	- 1	
1 1	- 1	1	- 1
1 1 .	1	- 1	1
1 1	1	- 1	1
1 1	1	1	1
	1	1	1
	· 1	l	1
The present search report has been		. 1	1
The present search report has been draw	en up for all claims	1	1
THE HAGUE	Date of completion of the search	1	1
THE HAGUE CATEGORY OF CITED PROCUMENTS	19 July 155	Economic	
	19 July 1996		
X: particularly relevant if takes alone Y: particularly relevant if takes alone	T : theory or mind	Kousouretas	. 1
A	T: theory or principle under E: earlier patent document, wher the filling date D: document of the	ying the invention	
O : necessifical background O : necessifican disclosure F : intermediate of	D. J. THERE CALL	A	1
P : latermediate document	L: decourant cited in the app	plication Texton	1
	document of the name pates		1
	sectional seek being	It family, corresponding	
			1